

WHAT IS CLAIMED IS:

1. A stable isotonic reconstituted formulation comprising a protein in an amount of at least about 50 mg/mL and a diluent, which reconstituted formulation has been prepared from a lyophilized mixture of a protein and a lyoprotectant, wherein the protein concentration in the reconstituted formulation is about 2-40 times greater than the protein concentration in the mixture before lyophilization.
2. The formulation of claim 1 wherein the lyoprotectant is sucrose.
3. The formulation of claim 1 wherein the lyoprotectant is trehalose.
4. The formulation of claim 1 which further comprises a buffer.
5. The formulation of claim 4 wherein the buffer is histidine or succinate.
6. The formulation of claim 1 which further comprises a surfactant.
7. The formulation of claim 1 which is sterile.
8. A stable reconstituted formulation comprising an antibody in an amount of at least about 50 mg/mL and a diluent, which reconstituted formulation has been prepared from a lyophilized mixture of an antibody and a lyoprotectant, wherein the antibody concentration in the reconstituted formulation is about 2-40 times greater than the antibody concentration in the mixture before lyophilization.
9. The formulation of claim 8 wherein the antibody is an anti-IgE antibody.
10. The formulation of claim 8 wherein the antibody is an anti-HER2 antibody.
11. The formulation of claim 8 wherein the antibody is a full length humanized antibody.

12. The formulation of claim 8 which is isotonic.
13. A method for preparing a stable isotonic reconstituted formulation comprising reconstituting a lyophilized mixture of a protein and a lyoprotectant in a diluent such that the protein concentration in the reconstituted formulation is at least 50 mg/mL, wherein the protein concentration in the reconstituted formulation is about 2-40 times greater than the protein concentration in the mixture before lyophilization.
14. The method of claim 13 wherein the lyoprotectant is sucrose.
15. The method of claim 13 wherein the lyoprotectant is trehalose.
16. The method of claim 13 wherein the lyophilized mixture further comprises a bulking agent.
17. The method of claim 13 wherein the protein is an antibody.
18. A method for preparing a formulation comprising the steps of:
 - (a) lyophilizing a mixture of a protein and a lyoprotectant; and
 - (b) reconstituting the lyophilized mixture of step (a) in a diluent such that the reconstituted formulation is isotonic and stable and has a protein concentration of at least about 50 mg/mL.
19. The method of claim 18 wherein the protein concentration in the reconstituted formulation is from about 80 mg/mL to about 300 mg/mL.
20. The method of claim 18 wherein the protein concentration in the reconstituted formulation is about 2-40 times greater than the protein concentration in the mixture before lyophilization.
21. The method of claim 18 wherein lyophilization is performed at a shelf temperature maintained at about 15-30° C throughout the entire lyophilization process.
22. An article of manufacture comprising:

- (a) a container which holds a lyophilized mixture of a protein and a lyoprotectant; and
(b) instructions for reconstituting the lyophilized mixture with a diluent to a protein concentration in the reconstituted formulation of at least about 50 mg/mL.

23. The article of manufacture of claim 22 wherein the protein concentration in the reconstituted formulation is about 2-40 times greater than the protein concentration in the mixture before lyophilization.

24. The article of manufacture of claim 22 further comprising a second container which holds a diluent.

25. The article of manufacture of claim 24 wherein the diluent is bacteriostatic water for injection (BWFI) comprising an aromatic alcohol.

26. A formulation comprising a lyophilized mixture of a lyoprotectant and an antibody, wherein the molar ratio of lyoprotectant:antibody is about 100-1500 mole lyoprotectant:1 mole antibody.

27. A method for treating a mammal comprising administering a therapeutically effective amount of the formulation of claim 1 to the mammal, wherein the mammal has a disorder requiring treatment with the protein in the formulation.

28. The method of claim 27 wherein the formulation is administered subcutaneously.

29. A formulation comprising anti-HER2 antibody in amount from about 5-40 mg/mL, sucrose or trehalose in an amount from about 10-100 mM, a buffer and a surfactant.

30. The formulation of claim 29 further comprising a bulking agent.

31. The formulation of claim 30 wherein the bulking agent is mannitol or glycine.

32. The formulation of claim 29 which is lyophilized and stable at 30°C for at least 6 months.

Sub A3

33. The formulation of claim 32 which is reconstituted with a diluent such that the anti-HER2 antibody concentration in the reconstituted formulation is from about 10-30 mg/mL, wherein the reconstituted formulation is stable at 2-8°C for at least about 30 days.

34. The formulation of claim 33 wherein the diluent is bacteriostatic water for injection (BWFI) comprising an aromatic alcohol.

35. A formulation comprising anti-IgE antibody in amount from about 5-40 mg/mL, sucrose or trehalose in an amount from about 80-300 mM, a buffer and a surfactant.

36. The formulation of claim 35 which is lyophilized and stable at about 30°C for at least 1 year.

add A4

005280-96861560